

Office Action Summary	Application No. 10/595,413	Applicant(s) YAMAGUCHI ET AL.	
	Examiner John Pak	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-34 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 18-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>20100305</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1616

Applicant's attorney, Manette Dennis, telephoned the Examiner to apprise him of the fact that there is a preliminary claim amendment in this application. See the attached interview summary record. Accordingly, the previous Office action of 2/25/2010 is hereby vacated. The following new Office action is set forth.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted (i.e. elect one of Groups I, II, III, IV or V).

Group I, claims 18-19 (in part), 21, 24-25 (in part), and 26-28, drawn to compositions and preparations containing retinoic acid nanoparticles having a coating of calcium carbonate and average particle size of 5-300 nm. Group I, as it is the first claimed invention under lack of unity rules, includes the first method of making invention. Therefore, Group I also includes claim 20 (in part), which is drawn to method of making retinoic acid nanoparticles having a coating of calcium carbonate.

Group II, claims 18-19 (in part), 22, 24-25 (in part), and 29-31, drawn to compositions and preparations containing retinoic acid nanoparticles having a coating of zinc carbonate and average particle size of 5-300 nm.

Group III, claims 18-19 (in part), 23, 24-25 (in part), 32-34, drawn to compositions and preparations containing retinoic acid nanoparticles having a coating of calcium phosphate and average particle size of 5-300 nm.

Group IV, claim 20 (in part), drawn to method of making retinoic acid nanoparticles having a coating of zinc carbonate.

Group V, claim 20 (in part), drawn to method of making retinoic acid nanoparticles having a coating of calcium phosphate.

The inventions listed as Groups I to V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

Under lack of unity rules, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” is defined as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The “contribution over the prior art” is considered with respect to novelty and inventive step.

Here, a 2002 article by Yamaguchi et al. (Document 3 on page 2 of the IDS of 7/8/2007) discloses nanoparticles comprising micelles of retinoic acid with a core-shell structure in which calcium carbonate coats the surface of the retinoic acid. Diameter of the nanoparticles is reported as approximately 125-164 nm. The nanoparticles showed sustained release properties. See pages 1-2.

Clearly, nanoparticles comprising micelles of retinoic acid coated with calcium carbonate and having an average particle size as claimed were known prior to the effective filing date of this application. Further, WO 93/15720 appears to distinguish calcium from other metals such as zinc and carbonates from phosphates in stabilizing liposomes (page 3, lines 6-24). Thus, there is no technical relationship among the claimed inventions involving one or more of the same or corresponding special technical feature, which special technical feature defines a contribution over the prior art.

Art Unit: 1616

Accordingly, the inventions lack a unity of invention and applicant is required to elect one of the inventions for examination on the merits.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to John Pak whose telephone number is **(571)272-0620**.

The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John Pak/
Primary Examiner, Art Unit 1616